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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,287	09/24/2003	Gary Karlin Michelson	101.0092-02000	6591

22882 7590 03/17/2005

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EXAMINER	
BARRETT, THOMAS C	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/669,287	MICHELSON, GARY KARLIN
	Examiner	Art Unit
	Thomas C. Barrett	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 29, 2004 have been fully considered but they are not persuasive.

The Applicant has traversed the double patenting rejection over Application No. 10/669,291, now U.S. Patent No. 6,793,679. The Applicant argues that '679 was a divisional application of the '458 because they were separate species as noted in a Restriction Requirement in the '458 patent. However, the Applicant fails to argue why this information overcomes the obviousness-type double patenting rejection. The provisionally rejected claims of the present application are broader and encompass the limitations of the claims cited. For example, claim 1 is generic to both claim 1 of '458 and claim 1 of '679. The original restriction was proper because there was no generic claim encompassing both restricted species.

Contrary to the Applicant's arguments, Nolan does not disclose that the "in a collapsed position the implant widths (i.e., heights) are the same because of the use of a clip C." Nolan only states that the clip "***can be*** provided and received in holes 76 and 78 to cause the legs 18' and 20' to look like legs 18 and 20." (emphasis added).

Regarding the applicant's argument that Nolan explicitly teaches away from the presently claimed invention, MPEP 2145 states: "A known or obvious composition does not become patentable ***simply because it has been described as somewhat inferior to some other product for the same use.***" Therefore, though Nolan discloses that the ends having the same width is preferred, this does not constitute "teaching away".

Nolan may imply in the background that "one-piece, frusto-conical shaped implants" are "difficult to install", but this does not constitute an explicit teaching away; it is a less preferred method. In addition, the "frusto-conical" shape is anticipated as noted in the 35 USC § 102 rejections. Arguments of "teaching away" are for overcoming 35 USC § 103 rejections. As noted previously, Nolan does disclose that widths 26 and 28 in figure 3 can be of different sizes, therefore the shape may be frusto-conical. Furthermore, the method of implanting as disclosed by Nolan states, "***Preferably***, the width W' of the second portion 18 is approximately equal to the width of the first portion 16." (emphasis added).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 13, 33, 54-92 and 94-96 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9, 11, 13-20, 24-55 of copending Application No. 10/669,291, now U.S.

Patent No. 6,793,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention is more broadly claimed than '291.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-72, 74-76 and 84-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Nolan (6,117,174) as cited in Applicant's IDS. Nolan discloses a threaded expansile spinal fusion implant with a portion of a frusto-conical shape and an expanding disc (Fig. 17). The implant can be cylindrical or frusto-conical in its unexpanded position. Col. 4 lines 21-23 discloses that widths 26 and 28 in figure 3 can be of different sizes, therefore the shape may be frusto-conical. The threads act as bone-engaging projections that allow for linear insertion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Ray et al. (4,961,740) as cited in Applicant's IDS. Nolan discloses a threaded expandable spinal fusion implant however fails to disclose the use of hydroxyapatite as a material for the implant. Ray et al. teaches the use of hydroxyapatite as a material for a spinal fusion implant, which is useful as a bone-inducing substance (col. 4, lines 46-56). It would have been obvious to one of ordinary skill in the art to combine the teaching of hydroxyapatite as a material for a spinal fusion implant, as taught by Ray et al., to the spinal fusion implant as per Nolan, which is useful as a bone-inducing substance. Also Nolan fails to disclose the use of a snap fit cap for the ends of the implant. Ray et al. teaches the use of snap-fit caps for the ends of the implant (col.6, line 56) to retain bone-inducing substance when it is packed into the implant (col. 4, lines 20-23). It would have been obvious to one of ordinary skill in the art to combine the teaching of snap-fit caps for the ends of the implant, as taught by Ray et al., to the spinal fusion implant as per Nolan, to retain bone-inducing substance when it is packed into the implant.

Claims 77-83 and 89-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of would be obvious to one of ordinary skill

in the art. Nolan discloses a threaded expandable spinal fusion implant however Nolan fails to disclose the use of bone, genes coding or bone morphogenetic protein as a material for the implant. It is well known to one of ordinary skill in the art to use bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, to induce bone ingrowth into the implant. It would have been obvious to one of ordinary skill in the art to combine the teaching of bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, as is well known in the art, to the spinal fusion implant as per Nolan, to induce bone ingrowth into the implant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571)

272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Barrett
Examiner
Art Unit: 3738